

Amendments to the Drawings

Applicant respectfully requests that change of reference character “21” for the expansion screw to reference character “22” in FIG. 2 be approved by the Examiner in the above-identified application.

The attached sheet (1) of replacement drawings includes changes to FIG. 2. This sheet replaces the original sheet including the same figures.

Attachment: One replacement sheet of drawings

Remarks

A. Pending Claims

Claims 15-34 are pending. Claims 20, 26, and 34 have been amended.

B. Objections

The drawings were objected to for failing to comply with 37 CFR 1.84(p)(4). FIG. 2 has been amended for clarification. Applicant submits no new matter has been added to the drawing.

The Office Action states “drawings 6c and 6d were not received with the application.” The specification has been amended to remove all reference to FIGS. 6c and 6d.

One replacement sheet of drawings is attached following page 18 of this response.

C. Amendment to the Specification

The specification has been amended for clarification and to reflect the change in reference number “21” for the expansion screw to reference number “22”. Applicant submits no new matter has been added to the specification.

D. The Claims Are Not Indefinite Pursuant To 35 U.S.C. §112, Second Paragraph

Claims 20, 26, and 34 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claims 20, 26, and 34 have been amended for clarification. Applicant submits claims 20, 26, and 34 are definite.

E. The Claims Are Not Anticipated by Sertich Pursuant To 35 U.S.C. §102(b)

Claims 15-18, 21-24, 27-31, and 33 were rejected under 35 U.S.C. §102(b) as being unpatentable over U.S. Patent No. 5,800,550 to Sertich (hereinafter “Sertich”). Applicant respectfully disagrees with these rejections.

The standard for “anticipation” is one of fairly strict identity. A claim can only be anticipated if each and every element set forth in the claims is found to be either expressly or inherently described in the cited art. *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 728, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987), MPEP §2131.

Independent claim 15 describes an intervertebral implant that include a combination of features including, but not limited to, the features of:

an expansion member configured to be advanced through an opening in a side of the cage element to expand the intervertebral implant by elevating the insert and moving a portion of the insert through the opening in the superior surface of the cage element, thereby increasing a height of the intervertebral implant and allowing the superior surface of the insert to engage the second vertebra of the human spine

Independent claim 21 describes intervertebral implants that include a combination of features including, but not limited to, the features of:

an expansion member configured to be advanced through an opening in a side of the cage element to elevate at least a portion of the insert through the opening in the superior surface of the cage element, thereby increasing a height of the intervertebral implant and allowing the superior surface of the insert to engage the second vertebra of the human spine.

Independent claim 27 describes intervertebral implants that include a combination of features including, but not limited to, the features of:

an expansion member configured to be advanced through a third opening in the cage element to expand the intervertebral implant by engaging the first

insert and the second insert after the intervertebral implant is positioned between a first vertebra and a second vertebra of the human spine, wherein engaging the first insert comprises moving a portion of the first insert through the first opening of the cage element such that an inferior surface of the first insert engages the first vertebra of the human spine, and wherein engaging the second insert comprises moving a portion of the second insert through the second opening of the cage element such that a superior surface of the second insert engages the second vertebra of the human spine

The Office Action states:

an insert (70) comprising a superior surface (74) and an inferior surface (y2), wherein the insert is configured to be positioned in the cage element such that the inferior surface of the insert is inside of the cage element and the superior surface of the insert is outside of the cage element (see Figure 1A); and an expansion member (98, 114, 118) configured to be advanced through an opening (44) in a side of the cage element to elevate at least a portion of the inset through the opening in the superior surface of the cage element

Sertich does not appear to teach or suggest the combination of features of claims 15, 21, or 27 including, but not limited to, the feature of: “an expansion member.” Sertich appears to teach a support body with anchoring pegs, which appear to be inserted into a prepared disc space using a tool. Sertich does not appear to teach or suggest, for example, that the tool is part of the prosthetic device as stated in the Office Action. For example, Sertich states:

The device comprises an inert rectangularly shaped support body for seating on hard end plates of vertebrae, the support body having solid top and bottom faces. The shape is narrower in width than in height. This design allows placement in the disc space along the narrow side, then rotation of the device 90° to simultaneously lock the device in position, and distract the collapsed disc space. To avoid further dislodgement, anchoring pegs are movably mounted in the top and bottom faces of the support bodies. The pegs preferably comprise a body having a solid proximal end and an apertured distal end. The proximal end is tapered to allow extension of the pegs into the adjacent vertebrae by the movement of a piston of the insertion tool.
(Sertich, column 2, lines 36-48)

Once the body is correctly positioned between the vertebrae, the several pegs 70 therein are extended into the opposing surfaces of the two vertebrae. To this end, the piston 114 of the tool 98 is advanced so as to urge the opposing tapered surfaces 72 of the first set of pegs 70 away from each other and into the opposed vertebrae. Once these pegs have been advanced to their full extent, they are locked in position via the securing means 80. Then the piston 114 can be further advanced down the bore 44 until it encounters the opposed tapering surfaces 72 of

the second pair of pegs 70. As the piston is advanced forward in the tool 98 via the threaded stem 110, it will cause the second pair of pegs 70 to also extend into the opposed vertebrae and eventually be locked in position. Thereafter, the piston 114 can be retracted via its threaded stem 110 by reversing the direction of rotation thereof.

(Sertich, column 8, lines 36-50)

The combination of the features of claims 15, 21, and 27 including an “expansion member” does not appear to be taught or suggested by Sertich. As such, independent claims 15, 21, 27 and the claims dependent thereon (claims 16-20, 22-26, and 28-33, respectively) are patentable over Sertich. Applicant respectfully requests removal of the rejections to the claims.

Claims 16, 22, and 28 state in part, “wherein intervertebral implant is configured such that the direction of movement of the expansion member is substantially perpendicular to the direction of movement of the insert.” For at least the reasons stated above, the combination of features of claims 16, 22, and 28 including, but not limited to, the feature of: “expansion member” does not appear to be taught or suggested by Sertich.

Claims 17, 23, and 29 state in part, “wherein the expansion member is configured to be advanced between a superior surface of the first insert and an inferior surface of the second insert.” For at least the reasons stated above, the combination of features of claims 17, 23, and 29 including, but not limited to, the feature of: “expansion member” does not appear to be taught or suggested by Sertich. Applicant respectfully requests removal of the rejections to claims 17, 23 and 29.

Claims 18 and 24 state in part, wherein the superior surface of the insert comprises osteoconductive mesh structure.” Claim 31 states in part, “wherein the superior surface of the second insert comprises osteoconductive mesh structure.”

The combination of features of claims 18, 24, and 31 do not appear to be taught or suggested by Sertich. Sertich appears to teach packing the hollow area of the support body with autologous cancellous bone or other material to promote bone ingrowth and fusion. For example, Sertich states,

Then the piston 114 can be retracted. The tool 98 can be removed from the body 30 by unthreading the threaded section 104 of the first handle section 100 from the bore 106 in the body. At that point, the central passageway 44 can be packed with autologous cancellous bone, or even with other material. If desired, a small conventional cap (not illustrated) can then be placed over the exposed intracanal opening, the opening 46 in the body 30, to seal this opening.
(Sertich, Column 7, lines 25-33)

As such, the combination of features of the claim including, but not limited to, the feature of: “wherein the superior surface of the insert comprises osteoconductive mesh structure” does not appear to be taught or suggested by Sertich. Applicant respectfully requests removal of the rejections to claims 18, 24 and 31.

Claim 30 states in part, “wherein the inferior surface of the first insert comprises osteoconductive mesh structure.” For at least the reasons stated above, Sertich does not appear to teach or suggest the combination of features of claim 30. Applicant respectfully requests removal of the rejections to claim 30.

Claim 33 states in part, “wherein expanding the intervertebral implant comprises increasing a height of the intervertebral implant.” Sertich does not appear to teach or suggest the combination of features of claim 33. Sertich appears to teach an implant of fixed dimensions and pegs that extend into vertebra. For example, Sertich states:

Thus the implant body is rectangular in shape and, as can be seen from a comparison of FIGS. 2 and 3, the body 30 is taller than it is wide. The body 30 can typically measure between 9 x 11 millimeters and 11 x 13 millimeters, which is the height of the typical human disc.
(Sertich, column 5, lines 40-45).

The support body is so sized as to span the disc space and prevent the adjoining vertebrae from approaching each other. The body 30 is inserted by means of the tool 98. To this end, the body 30 can be threaded onto the threaded tip 104 of the first handle section 100 of the tool 98.

Once the body is correctly positioned between the vertebrae, the several pegs 70 therein are extended into the opposing surfaces of the two vertebrae.
(Sertich, column 8, lines 18-38).

The combination of feature of claim 33 including, but not limited to, the feature of: “wherein expanding the intervertebral implant comprises increasing a height of the intervertebral implant” does not appear to be taught or suggested by Sertich. Applicant respectfully requests removal of the rejection to claim 33.

F. The Claims Are Not Obvious Over Sertich In View of Larsen et al. Pursuant To 35 U.S.C. §103(a)

Claims 19, 25, and 32 was rejected under 35 U.S.C. §103(a) as being unpatentable over Sertich in view of U.S. Patent No. 5,782,832 to Larsen et al. (hereinafter “Larsen”). Applicant respectfully disagrees with this rejection.

In order to reject a claim as obvious, the Examiner has the burden of establishing a *prima facie* case of obviousness. *In re Warner et al.*, 379 F.2d 1011, 154 USPQ 173, 177-178 (C.C.P.A. 1967). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974), MPEP §2143.03.

The Office Action states:

Sertich discloses the invention substantially as claimed, however, Sertich does not disclose a raised portion of the inferior surface of the cage that will inhibit backout of the expansion member. Larsen et al. teaches such a projection in col. 8, lines 8-29 for the purpose of traversing movement with the interior of the implant. Thus it would have been obvious to one of ordinary skill in the art at the time the invention to include a raised portion of the inferior surface of the cage in order to inhibit backout of the expansion member by traversing movement with the interior of the implant.

Claims 19, 25, and 32 state in part, “wherein an interior surface of the cage element comprises a raised portion configured to inhibit backout of the expansion member after expansion of the intervertebral implant.”

Sertich in combination with Larsen does not appear to teach or suggest the combination of features of the claims 19, 25, and 32. As conceded in the Office Action, Sertich does not

disclose a raised portion of the inferior surface of the cage that will inhibit backout of the expansion member. Larsen does not teach or suggest the combination of feature of the claims including, but not limited to, the feature of: “an interior surface of the cage element comprises a raised portion configured to inhibit backout of the expansion member after expansion of the intervertebral implant.” As shown in FIG. 21, Larsen appears to teach pyramid-shaped projections on the exterior surface of the implant to engage vertebra. For example, Larsen states:

Referring now to FIGS. 21-24, there is illustrated another alternate embodiment of the spinal implant of the present disclosure. Implant 400 includes two support members, i.e., upper support member 402 and lower support member 404 having respective contacting surfaces 406, 408. Each contacting surface 406, 408 has a plurality of pyramid-shaped projections 410 which facilitate engagement with the vertebral end plates of the adjacent vertebrae "V₁, V₂" upon insertion within the intervertebral space "i".
(Larsen, column 8, lines 8-16).

Since Sertich does not appear to teach an expansion member and Larsen appears to only teach projections on the exterior surface of the implant to engage vertebra, Applicant submits there is no motivation or teaching in Sertich or Larsen to include a raised portion on the interior surface of the cage element configured to inhibit backout of the expansion member after expansion of the intervertebral implant.

Obviousness can only be established by “showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teaching of the references.” *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

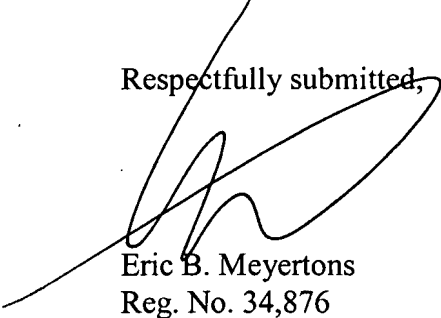
The features of claims 19, 25, and 32 including, but not limited to, the combination of feature of: “an interior surface of the cage element comprises a raised portion configured to inhibit backout of the expansion member after expansion of the intervertebral implant” does not appear to be taught or suggested by Sertich in combination with Larsen. Applicant respectfully requests removal of the rejection to claims 19, 25, and 32.

G. Additional Comments

Applicant submits that all claims are in condition for allowance. Favorable consideration is respectfully requested.

Applicant believes no fees are due with the filing of this document. If an extension of time is required, Applicant hereby requests the appropriate extension of time. If any fees are required, please appropriately charge or credit those fees to Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C. Deposit Account Number 50-1505/5943-00300/EBM.

Respectfully submitted,



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